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| EXAMINER | |
|---|---|
| AFTERGUT, JEFF H | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1733 | |

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/057,667 | SMITH, SCOTT | |
| | Examiner | Art Unit | |
| | Jeff H. Aftergut | 1733 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 5, 6, 8-11, 14, 16, 17, 20, 21, 23, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al (US 5,824,040) in view of any one of Nolting et al (US 6,488,701, newly cited), Shull et al (US 6,143,022, newly cited) or Schmitt (US 5,527,353, newly cited) either combined alone or optionally further taken with any one of Pinchuk '913 (newly cited), Pinchuk '958 (newly cited), or Pinchuk '877 (newly cited).

Cox et al suggested that it was known at the time the invention was made to form a stent graft 71 assembly by first attaching a series of diamond shaped elements 73 which form a stent component to a strip of liner material 75 which forms the graft component via a sewing operation, see Figure 5E in the manufacture of a stent graft assembly. Cox et al suggested this planar ribbon was then wound over a mandrel 77 (helically) of the desired size and adjacent edges of the ribbon were sewn to each other or otherwise permanently joined together. See column 12, lines 19-55, Figure 5E. The reference suggested that those skilled in the art would have formed an essentially flat preformed assembly of a stent and a graft component and then helically wound the same to form a stent graft assembly in tubular form. The reference, however, appears to have formed the strip of graft material from a woven strip of material onto which the stent component was secured with suture thread in the operation. There is no indication that one skilled in the art would have formed the graft component from a strip of plastic

material (like a ptfe or e-ptfe tape of material). Additionally, while it does appear that there are cross over of the stent wire in the assembly and the assembly is essentially flat in nature (the cross over would not have resulted in an appreciable third dimension to the finished planar strip of graft and stent material) the use of an undulated stent material which lacked cross over was known in the art wherein such material was helically wound to form a stent component.

Concerning the use of a tape of ptfe or e-ptfe in place of the woven strip of material (i.e. the use of a material for the strip of material which was formed from a polymer which was manufactured via extruding, casting, or molding rather than the use of graft material in the form of a woven strip of material), the reference to any one of Nolting et al (US 6,488,701, newly cited), Shull et al (US 6,143,022, newly cited) or Schmitt (US 5,527,353, newly cited) are cited. Each of Nolting et al, Shull et al or Schmitt suggested that it was known in the art of manufacturing a graft to form the same into a tubular shape by winding and sintering a ptfe or e-ptfe tape (which presumably was formed in a conventional manner via extrusion of casting of the polymer to for the same into a tape form, note applicant is hereby given Official Notice that this is the typical manner in which ptfe and e-ptfe tapes were formed). More specifically, Nolting et al suggested that a thin walled graft would have been formed by winding successive helical windings 70 of thin polymeric tape of ptfe or e-ptfe with an overlap in the tape followed by sintering the wrapped mandrel assembly (see column 7, line 58-column 8, line 22, column 10, lines 33-42, and column 11, lines 13-25. It should be noted that in Nolting et al the graft material was subsequently associated with a stent assembly to

form a stent graft assembly. The reference to Shull et al suggested that one skilled in the art at the time the invention was made would have applied a tape upon the mandrel and done so via helically winding. Following the helical winding operation, the reference suggested one skilled in the art would have sintered the ptfe wound tape in order to form a tubular graft component. The applicant is more specifically referred to column 7, lines 3-30, examples 1 and 2. The reference to Schmitt suggested that one skilled in the art at the time the invention was made would have formed a tubular inner graft component from e-ptfe tape with was wound upon a mandrel and sintered to yield a tubular graft component. The reference to Schmitt additionally suggested that those skilled in the art at the time the invention was made would have incorporated a fabric about the interiorly disposed wound tube formed from the sintered tape of ptfe or e-ptfe. The reference suggested that those skilled in the art at the time the invention was made would have attached the exterior fabric or textile layer to the inner graft material by stitching, by adhesive, or by other mechanical means, see column 3, lines 15-18. Applicant is referred to column 2, lines 55-64 for the use of e-ptfe for the tape material which was wound upon the mandrel and column 7, lines 26-49 for the formation of the graft component via the winding of the tape component about the mandrel. As evidenced by any one of Nolting et al, Shull et al or Schmitt, the artisan would have understood that the material utilized for the graft component in Cox et al would have not only included the specified woven strip but also a tape of ptfe or e-ptfe would have been suited for the operation (as noted above one skilled in the art would have understood that ptfe or e-ptfe tapes would have been formed via extruding, casting or molding the

polymeric materials and applicant was given Official Notice that this is the conventional manner in which these tapes were formed in the prior art). It should be noted that the crossing over of the stent wire to for the stent with the diamond pattern in Cox et al is deemed to qualify as a flat and planar stent component. It does NOT have a significant third dimension relative to its planarity. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the tape of ptfe or e-ptfe in place of the woven ptfe graft component of Cox et al as such was suggested by any one of Nolting et al, Shull et al or Schmitt in the operation of making the stent graft of Cox et al.

With regard to claims 5, 11,and 20 note that extruded tapes of ptfe or e-ptfe were known per se as tapes of ptfe or e-ptfe and the manner that one formed the same was known per se in the art (such was taken as conventional processing for forming these tapes). Regarding claims 6, 14, and 21 note that the winding in the references of any one of Nolting et al, Shull et al or Schmitt all overlap. Regarding claims 9, 10, 23, and 24, this is the construction of the stent component described by Cox et al. regarding claim 16, note that the references to any one of Nolting et al, Shull et al or Schmitt formed a tubular assembly from the winding operation. Regarding claim 26, note that the references to Nolting et al, Shull et al or Schmitt suggested attachment with adhesive of the reinforcing component to the graft member.

The combination failed to teach that one skilled in the art at the time the invention was made would have incorporated a stent wire arrangement wherein the stent wire did not cross over itself in the assembly (note that as addressed above the claims do not

appear to exclude the same in the "planar" and "flat" arrangement). However, in the event that one were to interpret the claims as to exclude the use of the stent wire with the cross over, the references to Pinchuk "913, Pinchuk '958, or Pinchuk '877are cited herein to show that the specified stent component was known at the time the invention was made wherein the stent component was formed from a single undulating wire and wherein the stent component was helically wound to form the prosthesis. Such would have been an art recognized equivalent for the stent component of Cox et al wherein the stent components were all helically wound to form a stent assembly on a mandrel. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the techniques of any one of Pinchuk "913, Pinchuk '958, or Pinchuk '877 to provide a suitable stent component in a stent graft assembly of Cox et al wherein the graft component was an extruded tape strip which was wound to form the graft arrangement as taught by any one of Nolting et al, Shull et al or Schmitt.

3. Claims 1- 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references ass et forth above in paragraph 2 further taken with either one of Shannon et al (5,928,279) or Brauker et al (6,517,571).

Cox et al is discussed in detail above. The reference failed to expressly state that the wire component was the stent material and that the tape and/or strip material was the graft material. However, in the art of stent grafts, it was known at the time the invention was made to incorporate a wire component for the stent as well as a plastic (polyethylene terephthalate) as the graft component in the manufacture of a stent graft. Additionally, it was well known to embed the stent component within two layers of graft

component material. Shannon et al as well as Brauker et al evidence such. More specifically, Shannon et al suggested that those skilled in the art would have disposed a stent component 14 formed of wire between two graft components 12 and 16 (where the graft components are made of ptfe). Such was a desirable arrangement for the stent graft as it would have presented a smooth interior and exterior surface for the stent graft assembly thus making insertion and retention in the body easier. Brauker et al (Figure 8C) suggested that it was known to dispose stent material 80 between an inner and outer sheet of graft material 81 formed from ptfe. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the materials of either one of Shannon et al or Brauker et al in the operation of Cox et al as such would have been recognized as conventional materials utilized by the ordinary artisan in the course of manufacturing a stent graft. Additionally, to provide the stent material such that it was encapsulated between the graft materials in strip form prior to winding would have been obvious to the ordinary artisan as: (1) Cox et al provided the completed assembly prior to winding the assembly about the mandrel, and; (2) the references to Shannon et al or Brauker et al suggested that in a stent graft assembly the stent materials would have been embedded between two graft materials. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the techniques of Shannon et al or Brauker et al in the operation of Cox et al to form a stent graft assembly.

With respect to claims 2-4, 12-13, 18-19, note that the reference to Shannon et al or Brauker et al suggested that one skilled in the art at the time the invention was made

would have provided graft material on either side of the stent material wherein one bonded the graft material in the regions which were open in the stent layer. regarding claims 6-7, 14-15, 21 and 22, the reference to Cox et al clearly envisioned the winding of the material about the mandrel in the formation of the stent graft and the assembly of the edges of the edges of the strip wound upon the mandrel. Note that the winding must either be overlapped and bonded at the edges or abutted and joined at the abutting edges of the material to make the tubular structure and one skilled in the art would have readily understood that either technique would have been suitable for forming the stent graft. Regarding claim 10, note that the stent material of Shannon et al and Brauker et al was clearly defined as a wire material. regarding claim 16, note that Cox et al clearly suggested that the material would have been wound into a tubular stent graft material. regarding claims 23 and 24, the reference suggested that one skilled in the art would have employed linked diamond shaped wires (Cox) for the stent assembly. Regarding claim 26, note that Shannon et al or Brauker et al suggested lamination of the two graft materials with the stent material disposed there between and one skilled in the art would have understood that the graft material in planar form would have been laminated together with the stent material disposed there between prior to winding in Cox et al.

4. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as set forth above in paragraph 2 further taken with Martin et al (6,361,637).

The references as set forth above in paragraph 2 suggested the overall arrangement for the stent graft, however they failed to teach that the stent wire material would have been formed from nitinol. However, in the art of making a stent graft

assembly, it was known to provide the stent component as an undulated wire which was formed from nitinol as evidenced by Martin et al, see Figures 14A-14F for Martin et al, column 9, lines 17-column 10, line 5 for the undulated configuration of the stent component and column 10, lines 32-35 for the use of nitinol for the wire component. It should be noted that in Martin et al the stent component in Martin et al was disposed between an inner graft 4 and an outer graft member 8 (which is a coupling member). It would have been obvious to one of ordinary skill in the art at the time the invention was made to select a suitable material for the stent component in a stent graft assembly wherein such materials would have included nitinol for the stent wire as well as providing the stent in undulating form as suggested by Martin in the operation of making a stent graft as set forth above in paragraph 2.

***Response to Arguments***

5. Applicant's arguments with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection.

The applicant is advised that the incorporation of an extruded or molded tape for the woven ptfe tape or strip in Cox would have been obvious to one of ordinary skill in the art at the time the invention was made as evidenced by any one of Nolting et al (US 6,488,701, newly cited), Shull et al (US 6,143,022, newly cited) or Schmitt (US 5,527,353, newly cited). Additionally, while it is not conceited that the process excluded the overlaying of stent wire components, the references to any one Pinchuk '913 (newly cited), Pinchuk '958 (newly cited), or Pinchuk '877 (newly cited) suggested such an arrangement for the stent component of the assembly. While it is agreed that the

reference to Cox et al suggested that one skilled in the art at the time the invention was made would have employed a strip which included a woven fabric strip as well as a stent component which included the diamond shaped stent wire (where it appears that the wire crosses over itself in the middle of the strip), the reference nonetheless suggested that when processing to make a stent graft assembly one skilled in the art would have known to assemble a flat strip component to a flat stent component as a preformed stent/graft assembly and then wound the same in order to form a tubular assembly. The artisan would have understood that various configurations of stent and graft components would have been suitable for processing in this manner and such would have included the use of the tape of ptfe or e-ptfe for the graft as well as the undulated stent component for the stent.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff H. Aftergut whose telephone number is 571-272-1212. The examiner can normally be reached on Monday-Friday 7:15-345 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Blaine Copenheaver can be reached on 571-272-1156. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeff H. Aftergut
Primary Examiner
Art Unit 1733

JHA
September 24, 2004